REMARKS

This amendment is presented contemporaneously with the interview of May 14, 2007 regarding this application and related cases 10/942,230 and 10/390,070. Claims have been amended and canceled hereby, so that the claims remaining are claims 1, 12, 15, 16, 18, 20, 22, 25, 26, 29 and 32. It was agreed at the interview of May 14, 2007 that these claims are allowable in view of this amendment and the concurrently filed Declaration under 37 CFR 1.132 and Terminal Disclaimer with respect to co-pending application 10/942,230.

REJECTION UNDER 35 USC §102

Of the claims rejected under 35 USC §102 based on anticipation by US Patent 4,463,755 to Suzuki ("Suzuki"), only claim 1 and its dependent claims 15 and 26 remain. Claim 1 has been amended to recite that the second conduit will retain the shape to which it is axially extended or contracted. Page 3, paragraph 6, of the Office Action of February 14, 2007, states that Suzuki "is silent with regards to the conduit[] being able to retain its shape after axial extension or contraction..." Applicants have discussed the importance of this element recited in applicants' claims at the interview and in arguments of record, and respectfully submit that the rejection under 35 USC 102(b) should be withdrawn.

REJECTIONS UNDER 35 USC §103

Of the claims rejected under 35 USC §103 based on obviousness over US Suzuki, WO 85/05277 to Clawson et al ("Clawson"), and/or US Patent 5,778,872 to Fukunaga (who is one of the present inventors, "Fukunaga"), only claims 12, 16, 18, 20, 22, 25, 29 and 32 remain, and these claims all depend from amended Claim 1, which is the only remaining independent claim. While the rejection under *35 USC §103* as stated in the Office Action would not apply to claim 1 provided the rejection under *35 USC §102* is overcome, it is respectfully submitted that for reasons of record and set forth herewith, Clawson does not teach a circuit in which *both* the inspiratory and expiratory limbs will retain different configurations to which they are bent. Clawson uses a single pleated tube to space the patient from supply and exhaust lines to minimize

pulling on the patient airway device. The inspiratory gas line and expiratory gas line 108 and 110 of Clawson's device between the machine and Clawsons manifold 98 will be inflated by the high pressure used and if bent will begin to straighten out under pressure. This could be extremely detrimental to a patient if it was connected to Clawson's manifold 98. Hence, Clawson used a single pleated tube to distance the patient from his manifold and tubing. One of ordinary skill in the art would not find it obvious to remove the coaxial portion of Clawson's device to replace portions of Suzuki as neither document recognizes and addresses the substantial flow property differences between a pleated tube and corrugated and whether or not *spontaneous* ventilation is possible with coaxial pleated tubes. As pointed out in the interview and in the record, Clawsons manifold 98 includes a nozzle 100 at the end of the inspiratory gas line that substantially interferes with flow. Only the high pressures used in high frequency pulsed ventilation, which is what Clawson's device is for, can overcome the resistance to flow in nozzle 100. This would bar a patient from getting sufficient air under spontaneous ventilation conditions, and could lead to death or serious hypoxic injury. However, this high pressures required by Clawson will cause tubes 108 and 110 in Clawson to expand and straighten. Due to the Clawson's teaching that "[t]here is no need to match [tubes 108 and 110] or cut them to matching lengths, if tube 108 is shorter than tube 110, the inspiratory gas line can disconnect – a strong teaching away from use of the Clawson device even for high frequency and pressure ventilation. If the outer tube is smaller, the pressures can cause Clawsons outer tube to disconnect at either the machine end or the manifold.

Claim 1 recites first and second pleated tubes connected at their distal ends to a common distal fitting, and the distal fitting is capable of detachable connection *directly* to a patient airway device selected from a mask, an endotracheal tube, a laryngeal mask, a laryngeal tube, and a nasal tube, and the breathing circuit meets the flow and compliance requirements for spontaneous and assisted ventilation. It would be dangerous to try to connect Clawson's manifold 98 directly to a patient airway device as (1) it would not provide sufficient oxygen under spontaneous ventilation conditions and (2) it would either pull the patient airway device (e.g., endotracheal tube inserted into

the neck) away or out from the patient or move the patient airway device. Further, the Clawson device would likely have a dangerous failure when connected to high pressures required to use Clawson's device for its intended use.

One of skill in the art would not find it obvious to modify Fukunaga or Suzuki to use co-axial pleated tubes in view of Clawson because the adjustable length of Clawson's coaxial portion is overridden by the pressures used by Clawson, which requires that Clawson add a "circuit element" formed of a single pleated tube between Clawson's manifold 98 and the patient. Further, none of the prior art addressed the substantial flow concerns of pleated tubing for use in a circuit for spontaneous ventilation, which concerns are multiplied in coaxial pleated tubing arrangement. The prior art is devoid of teachings that would lead or motivate one of ordinary skill in the art to modify coaxial breathing circuits to use pleated tubing, but rather the unpredictability of flow in pleated tubing discouraged its use (see for example the Nunn reference submitted in a prior IDS, which shows that pleated tubing causes turbulent flow at much lower flow rates than corrugated tubing). It is truly surprising that the present inventor discovered that a coaxial circuit of pleated tubing can provided spontaneous ventilation and has other surprising benefits, such as the ability to optimize the use of gases delivered to the patient versus gases delivered at the machine end of the circuit, along with numerous other benefits.

While breathing circuits appear to be simple constructs of tubing and fittings, the science underlying their development, use and improvements is complicated; inadequate function, improper design or construction, and/or damage to breathing circuits can lead to death or serious injury. Since breathing circuits supply both breathing air crucial to life as well as inhaled medications such as anesthetics, one of skill in the art is required to study complex biological systems, the physics of fluid and gas flow in the systems, and the chemistry of the system components and reactants. Thus, attempted improvements to breathing systems share the unpredictability of pharmaceutical research. Even small changes to prior art breathing circuits can lead to significant unexpected detrimental or beneficial effects, and significant research efforts, failures and expense are associated with making successful improvements to breathing circuits. While an improved breathing circuit may have only minor changes in tubing

and fitting dimensions and configurations over the closest prior art, the large number of patents for breathing circuits and their components reflects the inventive and patentable merit often associated with what appear to be small breathing circuit modifications. Further, the prior art often goes in opposite directions. For example, depending on the teaching, the distal end of the inspiratory tube in a unilimb circuit is either connected at its distal end to a distal fitting with the expiratory tube (in order to avoid dead space at the distal end of a circuit), or it is taught to disconnect the inspiratory tube from the distal fitting to prevent undesired detachment at the proximal end and avoid dead space during use (e.g., US Patent 4,265,235).

The change of just one tube from corrugated tubing to pleated tubing in a circuit or portion thereof is a significant modification to a breathing circuit due to the large variation in flow characteristics between corrugated and pleated tubing. Pleated tubing can extend to over three to five times its compressed or folded length, and will retain the angle, shape and conformation to which it is manipulated. In contrast, corrugated tubing maintains a substantially consistent length and volume, which can lead to undesired disconnection of such tubing undergoing tension such as that encountered in a typical operating room (e.g., during routine manipulation and/or by the circuit being stepped on). The large differences in pleated tubing and corrugated tubing pose significant unpredictable performance variations and construction challenges in exchanging corrugated tubing with pleated tubing, which discouraged the use of pleated tubing as disclosed by the present application. Despite pleated tubing being available for more than 20 years, no one of skill in the art taught or suggested a unilimb circuit wherein both the inspiratory and expiratory tubes are formed of pleated tubing as recited in the present claims

The invention recited by claim 1 is embodied in a commercial product that has achieved commercial success in a short period of time, which can be substantially attributed to the many benefits of the present inventions and associated unexpected results. The benefits of the present inventions and the long felt needs met by the present inventions further establish these inventions to be both novel and non-obvious. Further, the claimed inventions solve many problems that prior circuits cannot solve.

The unilimb circuit of the present inventions provide a breathing circuit that is multi-functional, having a variable length circuit (extended and contracted) and its flexibility allows it to retain a desired shape, angle or conformation, while allowing spontaneous and assisted ventilation. The ability to adjust the length of the breathing circuits of the present inventions during use produces tremendous advantages and benefits since the same circuit can be extended, for example if the position of the patient needs to be changed during surgery, or when the ventilator or anesthesia machine is moved farther away, without fear of excessive pulling at fittings that can lead to undesired disconnection. Likewise, the circuit can be compressed to avoid an undesired draping if the anesthesia machine is relocated closer to the patient. This can be done without the need to use different size circuits demanded by use of prior art circuits. The circuits of the present inventions solve multiple problems of prior art circuits, and have the following benefits over prior art circuits:

a) Significant cost savings:

No need to use and dispose of several circuits for the same surgical procedure when the anesthesia machine or ventilator needs to be relocated or when the position of the patient needs to be changed during surgery.

b) Safety:

- Avoids and/or minimizes chances of occlusion due to excessive draping (this often happens when the anesthesia machine is moved and the machine rests on the circuit or a health care provider steps on the circuit).
- Avoids and/or minimizes chances of disconnections or misconnections during the operation, because the same connected circuit is utilized in a variety of lengths and circumstances.
- It maintains a desired conformation or shape of the tubing and maximum control over difficult positioning without pulling and disconnecting the circuit from the airway device such as the endotracheal tube; such disconnection can be crucial as the patient may not receive sufficient oxygenation and/or anesthetics during the procedure.

- The flexibility of the circuit also avoids pushing and/or moving the endotracheal tube which may cause injury of the patient's vocal cord, larynx etc.

c) Storage space and inventory cost savings:
- Only one circuit size needs to be stored.
- Inventory becomes significantly simple.
- Storage space is greatly reduced.

d) One size fits all usages and simplifies inventory:
- Only one size circuit needs to be manufactured.
- Filling orders/requests becomes much simpler and economical for the manufacturer/distributor with less chance of errors.

e) Packaging and shipping:
- Packaging is more compact.
- Shipping becomes simpler and less expensive because the size of the shipping containers are smaller and lighter in weight.

f) Controls the inspiratory/delivery anesthetic concentration ratio:
- Controls airflow volume of the conduits by extending or contracting the breathing conduits.
- Avoids under-anesthetizing the patient during low-flow anesthesia.
- Provides significant savings in anesthetic gases.

g) Convenience:
- Much more convenient for the user, the procurement department of the hospital, and the manufacturing company.

In contrast, the prior art unilimb breathing circuits, such as those taught in the cited Suzuki and Fukunaga patents, have different structures, and their function is limited to a predetermined length circuit as they cannot extend and contract and do not retain a desired angle, shape or conformation.

As discussed above, one of skill in the art would not be led to combine Clawson's teachings with that of Suzuki and/or Fukunaga (or other prior art) because Clawson

cannot provided spontaneous ventilation, is inoperative and/or dangerous when used for its intended purpose, and teaches away from the present invention.

For almost two decades since Clawson was published no one of skill in the art recognized that Clawson's manifold could be replaced with a distal fitting that can be directly attached to a patient airway device and that the higher pressures required for Clawson's device and use were not necessary to overcome concerns about insufficient and unpredictable air flow through two coaxial pleated tubes at lower pressures and flows used for conventional spontaneous and assisted ventilation.

One of skill in the art would be taught away from the present invention by Clawson's teaching of distancing the patient from the supply and exhaust conduits of its circuit (which is also a controversial teaching of increasing dead space – considered undesirable in numerous prior art publications), and would not be led to modify Clawson's inoperative device to accomplish the present inventions due to the different function and requirements of Clawson (i.e., high pressure pulsing versus spontaneous and assisted ventilation). It is clear that the present invention is not obvious to one of ordinary skill in the art over Clawson in combination with Suzuki or with other prior art since almost two decades passed after Clawson's publication and that of Suzuki.

In fact, numerous teachings of unilimb circuits have been available for over 35 years. Unilimb coaxial circuits have been used clinically since about 1972. For example, the Bain circuit disclosed in US Pat. No.3,856,051, issued in 1974, and the F circuit disclosed in US 4,265,235, issued in 1981, both of which predate Clawson. Yet, despite these prior teachings of unilimb circuits and pleated tubing being known, none of the cited documents (i.e., Suzuki, Clawson, or Fukunaga (the present inventor)) recognized that pleated tubing could be used as claimed to achieve the claimed circuit with its numerous benefits. Furthermore, after the disclosures of the Clawson and Suzuki references, numerous circuit manufacturing companies and researchers in the field sought to improve unilimb circuits as demonstrated by the following U.S. patents: 4,621,634, issued to Nowacki et al. on November 11, 1986; 4,637,384, issued to Schroeder on January 20, 1987; 4,967,744, issued to Chua on Nov. 6, 1990; 5,121,746, issued to Sikora on June 16, 1992; 5,284,160, issued to Dryden on February 8, 1994; 5,404,873, issued to Leagre et al. on April 11, 1995; 5,722,391, issued to Rosenkoetter

et al. on May 3, 1998; 5,778,872, issued to Fukunaga et al. on July 14, 1998; 5,823,184, issued to Gross on October 20, 1998; 5,983,891, issued to Fukunaga on November 16, 1999; 5,983,894, issued to Fukunaga on November 16, 1999; 5,983,896, issued to Fukunaga on Nov. 16, 1999; 6,003,5511, issued to Fukunaga on December 21, 1999.

In fact, US Patent 5,823,184, issued to Gross on October 20, 1998, cites Suzuki and Clawson, and the cited Fukunaga patent is based on a patent application by the present inventor filed more than a decade after the publication of Suzuki and Clawson. **Yet, despite almost two decades passing since the publication of Suzuki and Clawson, none of the inventors of these patents, which certainly is a group including persons of at least ordinary if not superior skill in the art, developed an enabling teaching of the present claimed inventions despite the many benefits mentioned above.**

There are also unexpected benefits of the present invention not taught or suggested by the prior art. For example, the ratio of inspired concentration to delivered concentration of anesthetic gases can be optimized by adjusting the circuit volume. This leads to substantial savings of anesthetic gases among other benefits, including those discussed before. Just the cost savings made possible by the present inventions alone demonstrate that if the present inventions had been obvious they would have been introduced years before.

The commercial success of the present inventions also demonstrates that the present inventions are not obvious. The King Systems' web site advertises a circuit, the "UNIVERSAL FLEX2" made in accordance with the present invention which is being sold in place of some of the prior circuits covered by the cited Fukunaga patent, further demonstrating that the present inventions are not obvious over the prior art. (See: http://www.kingsystems.com/PRODUCTS/CircleCircuits/UniversalFlex2/tabid/91/Default.aspx).

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In view of the foregoing, it is respectfully requested that the pending claims as amended be allowed.

Date

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